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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,085	09/22/2003	Gary L. Bowlin	49122-0162	1270

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EXAMINER

KOSSON, ROSANNE

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,085

Applicant(s)

BOWLIN ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 10-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 3/26/04, 3/31/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicants' election of Group I, claims 1-9, in the reply filed on June 10, 2005 is acknowledged. Applicants' election of the species of natural materials, proteins, therapeutic substances and molecules in claims 2, 4, 6 and 7, respectively, is also acknowledged. Claims 10-23 and the remaining species in claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Claim 5 is also withdrawn as being drawn to a non-elected species. Applicants did not state specifically whether the elections were made with or without traverse, but, because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

No claims have been amended, added or canceled. Accordingly, claims 1-4 and 6-9 are examined on the merits herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claim 1 recites a composition comprising any electroprocessed material and any substance. Claim 2 recites that any electroprocessed material may be used if the material is natural. Claim 3 recites that the composition comprises at least any two electroprocessed materials if one natural and one is synthetic.

The specification discloses that the invention includes any material that forms any type of structure or structures during or after electroprocessing and that any electroprocessing technique may be used (see, e.g., pp. 3 and 10). The specification does not exclude electroprocessing of materials by exposure to any electric field, such as static electricity, power lines or a form of electromagnetic radiation (radio waves, light, radiation, x-rays). The specification does list a number of therapeutic substances that may be used in the electroprocessed composition (see pp. 19-24), but the claimed compositions encompass literally any substance- clothing, furniture, machinery, vehicles, etc. The materials disclosed in the working examples are limited to electrospun materials- collagen, collagen/PGA/PLA, PEVA, PLA and mixtures of PEVA and PLA. The substances disclosed in the working examples are limited to the therapeutic proteins FGF, VEGF and insulin, the cell type of osteoblasts and one tissue, cardiac tissue.

Consequently, there is no evidence that a representative number species of such large and varied genera- electroprocessed materials and substances were in the

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possession of the inventors at the time of filing. To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these; and (2) a representative number of species within the genus must be disclosed. Because only a limited number of electroprocessed materials and substances are disclosed, the claims fail to satisfy the written description requirement.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "further comprising placement of the composition in a bioreactor" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. What one does with the composition does not materially change the composition being claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Coffee (WO 98/03267, see also equivalent US 6,252,129). Coffee discloses electrohydrodynamically making solid, partially solid, or gel-like compositions of fibers that incorporate or have a core of an immiscible substance such as a biologically active ingredient or cells for applying to skin, a wound, a burn or a body cavity (see p. 2, 1st full paragraph; p. 3, last paragraph; and paragraph bridging pp. 5 and 6). These compositions are mats or webs (see p. 3, 1st full paragraph). The fiber mats may be prepared from naturally occurring polymers such as fibrin or collagen (see p. 6, 1st full paragraph) or from synthetic biodegradable polymers such as polylactic acid, polyglycolic acid, polyvinyl alcohol or polyhydroxybutyric acid (see p. 4, 3^d paragraph). The diameter of the fibers is about 10-20 microns (see p. 17, lines 7-8). As shown in Figures 9 and 10, when the fibers are formed into a three-dimensional shape, spaces are created around the fibers and between pairs or groups of fibers. The immiscible substances are located in the spaces between the fibers. The three-dimensional composition has enclosures that define these spaces. More than one type of electroprocessed fiber may be used to form a mat or web composition (see p. 18, 2^d full paragraph; paragraph bridging pp. 19 and 20; p. 23, 1st full paragraph; paragraph bridging pp. 32 and 33). Therefore, a holding of anticipation is required.

Claims 1 and 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Martin et al. (US 4,043,331). Martin discloses making a fibrillar mat with electrospun organic material (abstract) for use in particular as bandages. Various polymers may be used to form the fibers, such as thermoplastic polymers, or those that may be spun from dispersions or solutions (column 4, lines 26-44; column 5, lines 21-29). Various immiscible substances such as biological components can be incorporated within the mat (column 2, lines 35-46). The fibers have a diameter of 0.1 to 10 microns (see col. 3, lines 21-23). As shown in Figures 2-4, when the fibers are formed into a three-dimensional shape, spaces are created around the fibers and between pairs or groups of fibers. The immiscible substances are located in these spaces. The three-dimensional composition has enclosures that define these spaces. When water-soluble polymers are electrospun, the polymers are first cross-linked with a suitable reagent to make them at least partially insoluble in aqueous media (see col. 4, lines 38-44). Martin et al. also disclose that fibers may be electrospun from multiple types of dissolved polymers. Each type of polymer has its own favorable properties, and combining polymers allows fibers with desired characteristics to be produced in a controlled manner (see col. 1, lines 38-56). Accordingly, a holding of anticipation is required.

Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Doshi et al. ("Electrospinning process and applications of electrospun fibers," J Electrostatics 35:151-160, 1995). Doshi discloses making three-dimensional

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compositions of electrospun fibers from solutions of water-soluble polymers, biopolymers, and liquid crystalline polymers. The fibers have a diameter of 0.05 to 5 microns. The fibrous compositions can be used for applying insecticide to plants, as non-woven fabric, as a wound dressing material or as an artificial blood vessel (see p. 152, 2^d full paragraph, and p. 159). Thus, an immiscible substance such as an insecticide, a wound-treating composition or blood is incorporated into the composition. When fibers form a three-dimensional shape, such as a fabric, a wound dressing or a membrane, spaces are created around the fibers and between pairs or groups of fibers in which the immiscible substance is located. The three-dimensional shape has enclosures that define these spaces. Composite materials may also be produced by changing the composition of the spinning solutions successively so that layers of different polymers are deposited on top of each other. Accordingly, a holding of anticipation is required.

Claims 1-4 and 6-8 are rejected under 35 U.S.C. 102(e) as anticipated by Murphy et al. (US 2002/0172705), as evidenced by Koseki et al. (US 5,922,356). Murphy discloses a composition comprising electroprocessed fibers, collagen (a natural material), and electroprocessed synthetic polymers (e.g., polycarbonate, polystyrene, polyvinylchloride, etc.) that is produced by culturing fibroblasts in a cell or tissue culture vessel that is electrostatically charged. The fibroblasts produce collagen as an extracellular matrix (see paragraphs 33 and 34). Cells located within the composition produce therapeutic substances in the spaces between the fibers that are immiscible

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with the fibers (see paragraph 32). The diameter of the organized matrix around the cells is preferably 30 microns or more (see paragraph 63). As many fibers are present in the matrix (see Fig. 3), the diameter of each fiber is less than 20 microns. Koseki discloses that the diameter of collagen fibers reconstituted in vitro is less than 50 nm, while the diameter of collagen fibers in vivo is about 10-130 nm (see col. 1, lines 51-54). As noted above, when fibers form a three-dimensional shape, spaces are created around the fibers and between pairs or groups of fibers. Thus, the three-dimensional shape has enclosures that define these spaces. Therefore, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4 and 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267), Martin et al. (US 4,043,331), Doshi et al. ("Electrospinning process and applications of electrospun fibers," J Electrostatics 35:151-160, 1995) and Murphy et al. (US 2002/0172705) in view of Mechanic (US 5,332,475). The teachings of Coffee, Martin et al. Doshi et al. and Murphy et al. are discussed above. Although the cited references teach a composition comprising an electroprocessed natural material and a therapeutic protein substance that is composed of molecules, and although the cited references teach that the composition may comprise multiple electroprocessed materials- natural or synthetic- and cross-linked synthetic materials, Coffee, Martin et al. and Doshi et al. do not specifically disclose electroprocessed compositions comprising at least one natural material and at least one synthetic material. Coffee, Martin et al., Doshi et al. and Murphy et al. also do not disclose electroprocessed compositions comprising cross-linked natural polymers.

One of ordinary skill in the art at the time the invention was made would have been motivated to cross-link the fibrous mats of Coffee and Doshi et al. as suggested by Martin et al. because Coffee, Martin et al. and Doshi et al. make electroprocessed fibrous mats for similar purpose, as bandages incorporating biologically active material. Hence, it would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made to crosslink the electroprocessed fibrous mats for the expected increased strength and stability of cross-linking. One of ordinary skill in the art

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would know how to cross-link proteins, e.g., by treating them with formaldehyde or glutaraldehyde, which cross-links the ϵ -amino groups of lysine, hydroxylysine and other groups (see Mechanic, col. 1, lines 23-42). Proteins may also be cross-linked by treating them with a photocatalyst, such as methylene blue, methylene green, riboflavin or fluorescein, and oxygen and subjecting them to photooxidation (see Mechanic, col. 2, line 64, to col. 3, line 2, and col. 5, line 59, to col. 6, line 11). Cross-linking by the first method stiffens and strengthens collagen materials, while cross-linking by the second method reduces enzymatic degradation. Thus, it would have been obvious to the artisan of ordinary skill to cross-link electroprocessed protein materials for the advantages disclosed by Mechanic.

Regarding claim 3, which recites that the electroprocessed material comprises one or more natural materials and one or more synthetic materials, it would have been obvious to one of ordinary skill in the art at the time that the invention was made to prepare a composition as disclosed by Coffee or Murphy et al. containing one or more electroprocessed natural materials and one or more electroprocessed synthetic materials because Coffee, Martin et al. and Murphy et al. teach compositions comprising multiple electroprocessed materials. Coffee and Martin et al. teach that each material in the composition is selected because of its desired physical and chemical properties and that a selected combination of materials yields a controlled composition that has the properties desired, e.g., permeability, thickness, biocompatibility and biodegradability. One of skill in the art would recognize the benefits of a composition of electroprocessed materials comprising a natural material such as

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collagen for its biocompatibility, biodegradability and promotion of cell growth (as taught by Murphy et al.) and a synthetic material such as polyurethane, which is a wettable polymer commonly used in wound dressings. Polyurethane inhibits bleeding by promoting clotting, is porous and has a high surface area, which allows therapeutic substances to penetrate and blood from the wound to drain (see Martin et al., col. 2, lines 9-34).

In short, the prior art teaches electroprocessed cross-linked polymeric materials, including mixtures of natural and synthetic materials, that are formed into three-dimensional substances. These three-dimensional substances comprise therapeutic proteins or cells and used for the same purposes as the claimed invention.

Therefore, a holding of obviousness is required.

Double Patenting- Obviousness Type

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-17 and 25-46 of copending Application No. 09/991,373; claims 1-2 of copending Application No. 10/409,682; claims 1-17 of copending application no. 10/447,670; claims 1-4 of copending Application No. 10/630,624. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a genus of compositions (compositions comprising an electroprocessed material and a substance), while the copending applications recite, respectively, an engineered tissue comprising electroprocessed collagen and cells; a composition comprising an electroprocessed material and a substance, wherein the electroprocessed material is a fiber having a diameter of 20 microns or less; a matrix comprising electrospun collagen fibers having a diameter of 30 nm to 10 microns (the matrix may also comprise cells and has pores); and electroprocessed collagen produced by various techniques.

The instant invention and Application Nos. 09/991,373; 10/409,682 and 10/447,670 are each drawn to the same invention, although slightly different language is used in each set of claims. The claims of the instant application do not specify the fiber diameter or pore size in the compositions, but compositions with such fibers and pore sizes are species of the genus of compositions claimed. As noted in the citations of the prior art above, the compositions of the cited references comprise electroprocessed fibers having the same diameter and creating the same pore size as the various claimed compositions. Thus, these dimensions appear to be typical in the art, and one of

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ordinary skill in the art would expect the instant composition to be of the same dimensions as the compositions claimed in the copending applications.

Regarding claim 1 of Application Nos. 10/447,670 and 10/630,624, which recite, respectively, electrospun collagen and electroprocessed collagen, the instant specification teaches that these materials are typically processed to produce a layered three-dimensional matrix or scaffold that is impregnated with a bioactive therapeutic substance, such as a pharmaceutical compound or cells (see pp. 3, 17 and 23-24). Thus, the specification teaches that the claimed products of the copending applications are used to make the instant invention, which consequently is an obvious variation of those of the copending applications. Thus, a holding of obviousness is required.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

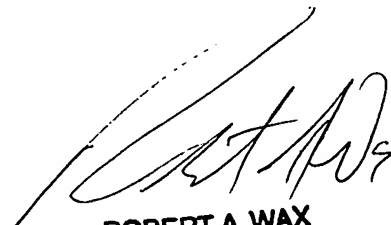
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk/2005-06-24



ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653